

We claim:

424/489
5 1. A particulate composition suitable for administration to a subject by means of a needleless syringe, said composition comprising particles that comprise a biologically active agent and a sustained-release material which controls release of the active agent to the subject following administration of the composition thereto, wherein said particles have a mean mass aerodynamic diameter of from about 0.1 to about 250 microns and an envelope density of from about 0.1 to about 25 g/cm³.

2. The composition of claim 1 wherein the mean mass aerodynamic diameter of the particles is from about 10 to about 100 microns, less than about 10% by weight of the particles have a diameter which is 5 microns more or 5 microns less than the mean mass aerodynamic diameter, the particles have an axis ratio of from about 3:1 to 1:1, the envelope density of the particles is from about 0.8 to about 1.5 g/cm³, and the particles exhibit less than about 25% reduction in mean mass diameter after delivery from a needleless syringe as determined in a particle attrition test.

3. The composition of claim 1 wherein the particles have a mean mass aerodynamic diameter of from about 20 to about 75 microns.

4. The composition of claim 1 wherein the biologically active agent is selected from the group consisting of drugs, vaccines, oligosaccharides, peptides, proteins and nucleic acids.

20 5. The composition of claim 1 wherein the sustained-release material is selected from the group consisting of poly(lactide), poly(glycolide), poly(carpolactone), poly(hydroxybutyrate), poly(lactide-co-glycolide) and poly(lactide-co-caprolactone).

6. A composition according to claim 1 which comprises a first set of particles comprising the biologically active agent in association with a first sustained-release material and a second set of particles comprising the biologically active agent in association with a second sustained-release material.

7. The composition of claim 1 wherein the particles are microcapsules comprising the biologically active agent encapsulated by a wall-forming sustained-release polymer material.

8. The composition of claim 1 wherein the particles are microspheres comprising a sustained-release polymer material.

9. A hermetically sealed single unit dosage or multidose container adapted for use in a needleless syringe, said container comprising the composition of claim 1.

10. A needleless syringe containing the composition of claim 1.

11. A method for delivering a biologically active agent to a subject, said method comprising:

(a) providing particles which have a mean mass aerodynamic diameter of from about 0.1 to about 250 microns and an envelope density of from about 0.1 to about 25 g/cm³ and which comprise the biologically active agent in association with a sustained-release material which controls release of the active agent to the subject following delivery thereto;

(b) accelerating the particles to a velocity from about 100 to about 3000 m/sec; and

(c) impacting the particles onto a surface of the subject thereby causing the particles to penetrate the surface and enter the subject.

12. The method of Claim 11 wherein the particles wherein the mean mass aerodynamic diameter of the particles is from about 10 to about 100 microns, less than about 10% by weight of the particles have a diameter which is 5 microns more or 5 microns less than the mean mass aerodynamic diameter, the particles have an axis ratio of from about 3:1 to 1:1, the envelope density of the particles is from about 0.8 to about 1.5 g/cm³, and the particles exhibit less than about 25% reduction in mean mass diameter after delivery from a needleless syringe as determined in a particle attrition test.

13. The method of Claim 11 wherein the particles have a mean mass aerodynamic diameter of from about 20 to about 75 microns.

14. The method of Claim 11 wherein the biologically active agent is selected from the group consisting of drugs, vaccines, oligosaccharides, peptides, proteins and nucleic acids.

15. The method of Claim 11 wherein the sustained-release material is selected from the group consisting of poly(lactide), poly(glycolide), poly(carpolactone), poly(hydroxybutyrate), poly(lactide-co-glycolide) and poly(lactide-co-caprolactone).

16. The method of Claim 11 wherein the composition comprises a first set of particles comprising the biologically active agent in association with a first sustained-release material and a second set of particles comprising the biologically active agent in association with a second sustained-release material.

17. The method of Claim 11 wherein the particles are microcapsules comprising the biologically active agent encapsulated by a wall-forming sustained-release polymer material.

5 18. The method of Claim 11 wherein the particles are microspheres comprising a sustained-release polymer material.

19. The method of Claim 11 wherein the particles are administered to the subject at a speed of 200 meters/second or greater.

20. The method of Claim 11 wherein the biologically active agent comprises 1 to 99 weight percent of the particle.

21. The method of Claim 11 wherein the particles are administered to a skin of the subject.

22. The method of Claim 11 wherein the particles are administered to a tissue of the subject.

20 23. The method of Claim 11 wherein the particles comprise two or more biologically active agents.

24. The method of Claim 11 wherein the subject is an animal.

25 25. The method of Claim 11 wherein acceleration of the particles is effected by entraining the particles into a flow of moving gas.

